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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,389	06/20/2003	Vepkhia Pilauri	03-337	4952

20306 7590 05/16/2006

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EXAMINER	
JOIKE, MICHELE K	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,389	PILAURI ET AL.	
	Examiner	Art Unit	
	Michele K. Joike, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *22-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/23/04, 8/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election of Group I in the reply filed on November 2, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-21 are pending and examined in this action.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
The hyperlink is on page 60.

Claim Objections

Claims 9, 12-14 and 21 are objected to because of the following informalities. Claim 9 is a duplicate of claim 7. In claims 12-14, the term "activatable" is used. "Activatable" is not a word. Claim 21 needs a "the" inserted between "in" and "cytoplasm" in the first sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,878,524.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants teach a method for detecting protein-protein interactions in a host cell cytoplasm comprising introducing a first protein or fragment fused with the N or C terminus of a repressor, introducing a second protein or fragment fused to a cytoplasm localization sequence wherein upon interaction, transcription of a gene is increased, and there is detection of increased transcription and protein-protein interaction. The method further comprises subjecting the cell to selective growth conditions and detecting increased growth or survival of cells. The cytoplasm localization sequence is

limited to a membrane targeting sequence, which can be a myristoylation or mitochondrial outer membrane targeting sequence. Specifically, the sequences can be SEQ ID NO: 1 or SEQ ID NO: 3. The first protein is further limited to a protein encoded by a cDNA or cDNA library, with the repressor fused to a plurality of cDNA library members. The second protein is further limited to a protein encoded by a cDNA or cDNA library, with the repressor fused to a plurality of cDNA library members. The second protein is a transcriptional activator or involved in transcriptional activation. Either protein is detectable or produces detectable metabolites. The transcriptional inhibitor can be Gal80p.

The gene expressed from a promoter that is regulated by or sensitive to the transcriptional inhibitor is one of a multiplicity of genes that encode detectable proteins. The promoter is limited to a GAL4 protein activatable promoter, which contains a UAS_{GAL} site. The gene encodes a detectable product. Increased transcription of the gene confers a growth advantage or distinguishes the cell in a detectable manner.

Applicants also claim a method for isolating the first or second fusion protein by detecting increased expression of the gene operably linked to a promoter that is regulated by or sensitive to the transcriptional inhibitor and isolating first or second protein. The first or second protein comprises a cDNA or cDNA library, with the repressor fused to a plurality of cDNA library members.

U.S. 6,878,524 (see entire patent) teaches a method for detecting protein-protein interactions in a host cell cytoplasm comprising introducing a first protein or fragment fused with the N or C terminus of a repressor, introducing a second protein or fragment

fused to a cytoplasm localization sequence wherein upon interaction, transcription of a gene is increased, and there is detection of increased transcription and protein-protein interaction. The method further comprises subjecting the cell to selective growth conditions and detecting increased growth or survival of cells. The cytoplasm localization sequence is limited to a membrane targeting sequence, which can be a myristoylation or mitochondrial outer membrane targeting sequence. Specifically, the sequences can be SEQ ID NO: 1 or SEQ ID NO: 3. The first protein is further limited to a protein encoded by a cDNA or cDNA library, with the repressor fused to a plurality of cDNA library members. The second protein is further limited to a protein encoded by a cDNA or cDNA library, with the repressor fused to a plurality of cDNA library members. The second protein is a transcriptional activator or involved in transcriptional activation. Either protein is detectable or produces detectable metabolites. The transcriptional inhibitor can be Gal80p.

The gene expressed from a promoter that is regulated by or sensitive to the transcriptional inhibitor is one of a multiplicity of genes that encode detectable proteins. The promoter is limited to a GAL4 protein activatable promoter, which contains a UAS_{GAL} site. The gene encodes a detectable product. Increased transcription of the gene confers a growth advantage or distinguishes the cell in a detectable manner.

It also teaches a method for isolating the first or second fusion protein by detecting increased expression of the gene operably linked to a promoter that is regulated by or sensitive to the transcriptional inhibitor and isolating first or second

protein. The first or second protein comprises a cDNA or cDNA library, with the repressor fused to a plurality of cDNA library members.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 2, 3, 4, 5, 7, 9 and 10 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 8, 9, 10, 11, 5 and 6 of prior U.S. Patent No. 6,878,524. This is a double patenting rejection. Claims 7 and 9 of the instant application both read on claim 5 of U.S. Patent No. 6,878,524. Claim 1 of the instant application and claim 1 of U.S. Patent No. 6,878,524 are commensurate in scope despite the additional language in the preamble of claim 1 of U.S. Patent No. 6,878,524. The additional language does not change the scope of the claim; it is just redundant verbiage.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 15 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,878,524. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 15 is generic to all that is recited in claim 17 of U.S. Patent No. 6,878,524. That is, claim 17 of U.S. Patent No 6,878,524 falls entirely within the scope of claim 15, or in other words, claim 15 is anticipated by claim 17 of U.S. Patent No. 6,878,524. Specifically, a gene encoding a detectable product in the instant application includes an exogenous reporter gene encoding a detectable product of claim 17 of U.S. Patent No. 6,878,524.

Claims 16-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18, 7 and 19 of U.S. Patent No. 6,878,524. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not

patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), *In re Longi*, 759 F.2d 887, 224 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Claims 16-18 are dependent on claim 1 and directed to a method for detecting protein-protein interactions in a host cell cytoplasm comprising introducing a first protein or fragment fused with the N or C terminus of a repressor, introducing a second protein or fragment fused to a cytoplasm localization sequence wherein upon interaction, transcription of a gene is increased, and there is detection of increased transcription and protein-protein interaction. Increased transcription of the gene confers a growth advantage or distinguishes the cell in a detectable manner. The transcriptional inhibitor can be Gal80p. The method further comprises subjecting the cell to selective growth conditions and detecting increased growth or survival of cells. Claims 18, 7 and 19 of U.S. Patent No. 6,878,524 are directed to a method for detecting protein-protein interactions in a host cell cytoplasm comprising introducing a first protein or fragment fused with the N or C terminus of a repressor, introducing a second protein or fragment fused to a cytoplasm localization sequence wherein upon interaction, transcription of a gene is increased, and there is detection of increased transcription and protein-protein interaction. Increased transcription of the gene confers a growth advantage or

distinguishes the cell in a detectable manner. The transcriptional inhibitor can be Gal80p. The method further comprises subjecting the cell to selective growth conditions and detecting increased growth or survival of cells.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele K Joike, Ph.D.
Examiner
Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER